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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/626,502	07/23/2003	Kyoichi Sumida	14633.1US01	1967	
	7590 01/17/2007 ann, Mueller & Larson,	EXAMINER			
P.O. Box 2902-0902			FETTEROLF, BRANDON J		
Minneapolis, MN 55402			ART UNIT	PAPER NUMBER	
		1642	··· —		
			MAIL DATE	DELIVERY MODE	
			01/17/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

# Advisory Action Before the Filing of an Appeal Brief

Application No.	Applicant(s)		
10/626,502	SUMIDA ET AL.		
Examiner	Art Unit		
Brandon J. Fetterolf, PhD	1642		

·	Brandon J. Fetterolf, PhD	1642	
The MAILING DATE of this communication appear	ars on the cover sheet with the d	orrespondence add	ress
THE REPLY FILED 27 December 2006 FAILS TO PLACE THIS	APPLICATION IN CONDITION F	OR ALLOWANCE.	
1.  The reply was filed after a final rejection, but prior to or on this application, applicant must timely file one of the follow places the application in condition for allowance; (2) a Not a Request for Continued Examination (RCE) in compliance time periods:	ring replies: (1) an amendment, affice of Appeal (with appeal fee) in (	idavit, or other evider compliance with 37 C	rce, which FR 41.31; or (3)
a) The period for reply expires <u>3</u> months from the mailing date	of the final rejection.		•
b) The period for reply expires on: (1) the mailing date of this Ar no event, however, will the statutory period for reply expire la	iter than SIX MONTHS from the mailing	g date of the final rejecti	on.
Examiner Note: If box 1 is checked, check either box (a) or (I TWO MONTHS OF THE FINAL REJECTION. See MPEP 70		E FIRST REPLY WAS F	ILED WITHIN
Extensions of time may be obtained under 37 CFR 1.136(a). The date thave been filed is the date for purposes of determining the period of extunder 37 CFR 1.17(a) is calculated from: (1) the expiration date of the set forth in (b) above, if checked. Any reply received by the Office later may reduce any earned patent term adjustment. See 37 CFR 1.704(b). NOTICE OF APPEAL	on which the petition under 37 CFR 1.1 ension and the corresponding amount hortened statutory period for reply orig than three months after the mailing da	of the fee. The appropri inally set in the final Offi	ate extension fee ce action; or (2) as
<ol> <li>The Notice of Appeal was filed on A brief in comp filing the Notice of Appeal (37 CFR 41.37(a)), or any exter a Notice of Appeal has been filed, any reply must be filed AMENDMENTS</li> </ol>	nsion thereof (37 CFR 41.37(e)), to	avoid dismissal of th	
3. X The proposed amendment(s) filed after a final rejection, b	out prior to the date of filing a brief.	will not be entered be	ecause
(a) They raise new issues that would require further cor			
<ul> <li>(b) ☐ They raise the issue of new matter (see NOTE below</li> <li>(c) ☒ They are not deemed to place the application in better appeal; and/or</li> </ul>	• •	ducing or simplifying	the issues for
(d) They present additional claims without canceling a c	corresponding number of finally rei	ected claims.	
NOTE: (See 37 CFR 1.116 and 41.33(a)).	·		•
4. The amendments are not in compliance with 37 CFR 1.12	21. See attached Notice of Non-Co	mpliant Amendment	(PTOL-324).
5. Applicant's reply has overcome the following rejection(s):			
<ol> <li>Newly proposed or amended claim(s) would be all non-allowable claim(s).</li> </ol>	owable if submitted in a separate,	·	<del>-</del>
7.  For purposes of appeal, the proposed amendment(s): a) the how the new or amended claims would be rejected is proved the status of the claim(s) is (or will be) as follows:	☑ will not be entered, or b) ☐ wi rided below or appended.	ll be entered and an e	explanation of
Claim(s) allowed:			
Claim(s) objected to:			
Claim(s) rejected: <u>1,8-12,14 and 16</u> .			
Claim(s) withdrawn from consideration: AFFIDAVIT OR OTHER EVIDENCE			
<ol> <li>The affidavit or other evidence filed after a final action, but because applicant failed to provide a showing of good and was not earlier presented. See 37 CFR 1.116(e).</li> </ol>	t before or on the date of filing a N I sufficient reasons why the affiday	otice of Appeal will <u>no</u> rit or other evidence is	t be entered necessary and
9. The affidavit or other evidence filed after the date of filing entered because the affidavit or other evidence failed to o showing a good and sufficient reasons why it is necessary	vercome <u>all</u> rejections under appe	al and/or appellant fai	ls to provide a
10.   The affidavit or other evidence is entered. An explanation	n of the status of the claims after e	ntry is below or attach	ned.
REQUEST FOR RECONSIDERATION/OTHER  11. The request for reconsideration has been considered but	t does NOT place the application is	o condition for allowar	re hecause:
	t dood to a place the application in	. John Morrior allowar	ico booduse.
12. Note the attached Information Disclosure Statement(s). ( 13. Other:	PTO/SB/08) Paper No(s).		

Art Unit: 1642

#### **DETAILED ACTION**

### Response to the Amendment

The Amendment filed on 12/27/2006 in response to the previous Final Office Action (9/27/2006) is acknowledged, but has not been entered. The amendment has not been entered because the limitation "as an agglutination accelerator, which is dissolved in a reagent, and is" would necessitate further consideration and/or search of the prior art, as well further consideration of patentability with respect to 35 USC 112, 1st paragraph and 112, 2nd paragraph.

Claims 1, 8-12, 14 and 16 are currently pending and under consideration.

The Declaration under 37 CFR 1.132 filed by the inventor, Kyoichi Sumida, on 12/27/2006 is insufficient to overcome the rejection of claims 1, 8-12, 14 and 16 under 35 U.S.C. 103(a) as being unpatentable over Eda et al. (U.S. 6248,597, 2001) and Shigenobu et al. (WO 02/018953, 2002) in further view of Craig et al. (US 4,401,765, 1983) as set forth in the last Office action because the declaration submitted under 37 CFR 1.132 fails to provide a good and sufficient reason why it is necessary and was not earlier presented. See 37 CFR 1.116(e).

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

#### Rejections Maintained:

Claims 1, 8-12, 14 and 16 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Eda et al. (U.S. 6248,597, 2001) and Shigenobu et al. (WO 02/018953, 2002) in further view of Craig et al. (US 4,401,765, 1983).

In response to this rejection, Applicants contend that the claimed invention exhibits superior results, and there is not motivation to combine the cited references. For example, Applicants point to Table of 1 of Applicants disclosure and compared these results with the corresponding polymers of Shigenobu et al, wherein Applicants assert that the results of Table 1 clearly show that the claimed invention is superior to the polymers disclosed in Shigenobu et al. for an assay of PSA.

Art Unit: 1642

Moreover, Applicants provide further experimental data in the form of the Declaration under Rule 1.132 to demonstrate the superior effects of the claimed invention.

As Applicants arguments appear to be solely drawn to the currently amended claims which have not been entered and the Declaration under 1.132 which has not been considered, such arguments have not been considered.

Therefore, NO claim is allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brandon J Fetterolf, PhD Patent Examiner Art Unit 1642

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SHANON FOLEY SUPERVISORY PATENT EXAMINER

TECHNOLOGY CENTER 1600